UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 9, 2001

MEMORANDUM

Subject: Efficacy Review for Oxonia Active (EPA Reg. No. 1677-129)
DP Barcode: D279450

From: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell PM-33/ Portia Jenkins
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: Ecolab Inc.
370 N. Wabasha Street
St. Paul MN. 55102

Formulation From Labels:

Active Ingredient(s)	% by wt.
Hydrogen peroxide	27.5
Peroxyacetic acid	5.8
Inert Ingredient(s)	66.7

I BACKGROUND

The applicant is applying for an amendment to the registration of their product to add a label claim as a sporicide against *Bacillus anthracis*. Oxonia Active is currently registered as an acid liquid sanitizer for food processing equipment, a disinfectant for use in healthcare facilities, animal care facilities, and farms, and as a sterilant for aseptic manufacturing and

packaging equipment. Product specific data against *Bacillus anthracis* was not generated nor submitted for this amendment. Instead, the applicant has provided an article from *The Veterinary Record*, to support the additional sporicidal claim.

Reviewed for this submission; a 1976 study from *The Veterinary Record*, and a proposed label, dated November 28, 2001.

II USE DIRECTIONS

Sterilization of Surfaces Contaminated with Anthrax

Oxonia Active is an effective sporicide against *Bacillus anthracis* (Anthrax) at 5 to 10 oz. per gallon of water (38.5 - 77 mL/liter), 2500 - 5000 ppm peroxyacetic acid in water up to 300 ppm (17.5 gpg) hardness at 68°F (20°C). One gallon of Oxonia Active concentrate will treat from 500 to 5,000 square feet (46 - 465 square meters) of surface. For increased contact time and application to overhead or vertical surfaces, apply Oxonia Active as a foam or thin film (gel).[1]

Areas of Use: Oxonia Active can be used in facilities such as Health Care facilities, schools, colleges, veterinary clinics, laboratories, industrial and commercial buildings, office buildings, recreational facilities, government buildings, food service and hospitality establishments, retail and wholesale establishments, beverage and food processing plants.

Oxonia Active is specifically designed to sterilize inanimate, hard, non-porous surfaces such as walls, floors, counter tops, machinery, furniture and to decontaminate personal protective equipment.

NOTE: Oxonia Active use solutions are compatible with stainless steel and aluminum surfaces. If use solutions are intended for use on other surface materials, apply to a small test area to determine compatibility before proceeding with use.

Product should only be used for decontamination of surfaces where anthrax is present. Product should only be used by personnel that are trained in anthrax decontamination (clean-up) procedures. Product should not be used as a preventative measure.

Do not use in air ducts, air handlers or duct work of heating, ventilation, air conditioning, and refrigeration systems.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

The Agency lists public-health related antimicrobial pesticides into three different categories: sterilants, disinfectants, and sanitizers. The term "decontaminant" does not represent a specific level of activity, however, for surfaces/items, it is considered a physical or chemical process used to make the surface/item safe for handling, use, or disposal. This

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[1] Additional directions for spray, foam, or gel applications are included. Contact time is listed as 20 minutes.

process may be achieved through sterilization or disinfection.

A "sterilizer" is an antimicrobial pesticide that destroys or eliminates all forms of microbial life in the inanimate environment, including bacterial spores. The term "sporicide" is deemed to be synonymous with "sterilizer." Since sterilization includes eradication of all living microorganisms, such claims are intrinsically related to protection of human health. The following apply to all products represented in labeling as sterilizing or sporicidal agents.

(1) Test requirements. The AOAC International Sporicidal Test is required for substantiating sterilizing claims. Sixty carriers-representing each of two types of surfaces (porcelain penicylinders and silk suture loops) are required to be tested against spores of both *Bacillus subtilis* ATCC 19659 and *Clostridium sporogenes* ATCC 3584 on three product samples representing three different batches, one of which is at least 60 days old (240 carriers per sample, a total of 720 carriers). Any sterilizing agent (liquid, vapor, or gas) which is recommended for use in a specific device must be tested by the AOAC Sporicidal Test in that specific device and according to the directions for use.

(2) Performance requirements. Killing on all of the 720 carriers is required. No failures are permitted. Data to support sterilizing claims must be confirmed by a second, independent laboratory of the applicant's choice (other than the laboratory which developed the original data). This confirmatory data must be developed on one sample of the product: Thirty carriers with each of the two types of surfaces (silk suture loops and porcelain penicylinders) against spores-of both *Bacillus subtilis* and *Clostridium sporogenes* (a total of 120 carriers) by the AOAC Sporicidal Test.

IV BRIEF DESCRIPTION OF THE SUBMITTED EFFICACY STUDIES

1. Hussaini, S. N., and Ruby, K.R.: "Sporicidal Activity of Peracetic Acid Against *B. anthracis* Spores". *The Veterinary Record, The Journal of the British Veterinary Association*, Vol. 98, January to June, 1976.

This article describes the use of peracetic acid (PAA) against spores of *Bacillus anthracis*. Two studies were conducted, one to assess the efficacy of PAA, at different concentrations, against *B. anthracis* spores, and the second to confirm the findings under simulated realistic conditions. The second study will not be described in this review, as it was conducted to simulate the reduction of spores in soil.

Suspension testing was conducted under five different contact times (0.5, 5, 10, 20, 30, and 60 minutes) three temperatures (4°C, room temperature, and 37°C), and five concentrations (0.1, 0.5, 1.0, 2.0, and 3.0%) of peracetic acid. After the contact time, a standard loopful of spore/treatment mixture was added to 10 mL of nutrient broth. Inoculated medium was incubated at 37°C for five days. Each subculture was then plated onto selective medium, incubated for 24 hours at 37°C and examined for growth of *B. anthracis*.

V RESULTS

Contact time	0.1%			0.5%			1.0%			2.0%			3.0%		
	4°C	RT	37°	4°C	RT	37°	4°C	RT	37°	4°C	RT	37°	4°C	RT	37°
0.5 minutes	c	c	c	c	c	c	c	c	c	c	c	-	-	-	-
5 minutes	c	c	c	c	c	c	c	c	30	c	-	-	-	-	-
10 minutes	c	c	c	c	c	-	c	-	-	5	-	-	-	-	-
20 minutes	c	c	c	c	-	-	-	-	-	-	-	-	-	-	-
30 minutes	c	c	c	c	-	-	-	-	-	-	-	-	-	-	-
60 minutes	c	c	c	c	-	-	-	-	-	-	-	-	-	-	-

c = confluent growth
30 & 5 = number of colonies
- = no growth
RT = room temperature (20°C)

VI CONCLUSIONS

The testing conducted using peracetic acid (PAA) against *B. anthracis* spores in suspension shows that PAA is not effective in killing spores at concentrations of 0.1% at all temperatures and contact times. However, at concentrations from 0.5% to 3.0%, the effectiveness of PAA at killing spores increased with concentration, temperature and contact time and was totally effective at a 3% concentration. The submitted information may demonstrate the presumptive efficacy of the product, however, for a sporicidal claim against *Bacillus anthracis*, the applicant must conduct product specific testing using the AOAC Sporicidal Activity of Disinfectants method against B. anthracis. At this time, the Agency has not determined whether *Bacillus globigii* would be acceptable as a surrogate for *Bacillus anthracis* ,therefore, surrogate testing is not being recommended.

Although the data presented for review are not sufficient for acquiring an amended label registration claim against *Bacillus anthracis*, the submitted information, together with the existing sporicidal data against *Bacillus subtilis* and *Clostridium sporogenes*, may be used as a basis for recommending the use of this product, under an emergency exemption, in an anthrax remediation plan. This plan would include; identification of a contaminated area, pre-cleaning of the area, treatment with the antimicrobial agent, post-treatment sampling and re-treatment of the contaminated area if anthrax spores are still present.

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